

I CLAIM:

1. A method for Calibration Algorithm Transfer comprising:

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(i) obtaining a first set of absorbance measurements of a set of calibrators on a First Apparatus that is in control at wavelengths from a first wavelength calibration table;

(ii) establishing a second wavelength calibration table on a second  
10 apparatus, said first and said second wavelength calibration table may be the same or different, and obtaining a second set of absorbance measurements of said set of calibrators on said Second Apparatus, at wavelengths from said second wavelength calibration table;

(iii) determining a first interpolated absorbance for said first  
15 absorbance measurements for at least one wavelength of a Standard Set of Wavelengths, and determining a second interpolated absorbance for said second absorbance measurements for said at least one wavelength of said Standard Set of Wavelengths,

(iv) deriving a First Linear Regression Equation for each of said at  
20 least one wavelength of said Standard Set of Wavelengths using said first and said second interpolated absorbance measurements;

(v) incorporating said First Linear Regression Equation and at least one Primary Calibration Algorithm onto said Second Apparatus.

25 2. A method of determining concentration of an analyte in a sample in a second apparatus comprising:

(a) performing a Calibration Algorithm Transfer according to the method of claim 1;

(b) measuring an absorbance of said sample on said second apparatus, and determining a sample interpolated absorbance for at least one wavelength of said Standard Set of wavelengths;

(c) adjusting said interpolated absorbance with said First Linear  
5 Regression Equation to obtain an Adjusted Interpolated Absorbance; and

(d) calculating a concentration for said analyte by applying said at least one Primary Calibration Algorithm for said analyte to said Adjusted Interpolated Absorbance.

10 3. The method according to claim 2, wherein in said step of obtaining (step (i)), and said step of measuring (step (b)), said set of calibrators and said sample are placed within a like vessel having optical properties substantially similar to that used for the Primary Calibration.

15 4. The method according to claim 2, wherein in said step of measuring (step (b)), said sample is any biological or non-biological fluid, and said analyte is any substance in said sample that can be measured.

5. The method according to claim 2, wherein in said step of measuring  
20 (step(b)), said sample is a solid, and said analyte is any substance in said sample for which an absorbance measurement can be obtained.

6. The method according to claim 3, wherein said vessel is selected from the group consisting of a pipette tip, a labeled test tube, an unlabeled test  
25 tube, blood bag tubing, a transparent sample container, and a translucent sample container.

7. The method according to claim 1, wherein in said step of obtaining (Step (i)), two or more calibrators are used.

8. The method according to claim 7; wherein said set of calibrators, used on both said First Apparatus and said Second Apparatus, are from the same batch.
- 5 9. The method according to claim 8, wherein said set of calibrators comprise any material suitable for simulating absorbances and for producing at least one of said First Linear Regression Equation.
- 10 10. The method according to claim 9, wherein said set of calibrators used on said First Apparatus are the same as said set of calibrators used on said Second Apparatus.
- 15 11. The method according to claim 1, wherein in said step of determining (step iii)), said Standard Set of Wavelengths comprises wavelengths from about 300nm to about 2500 nm.
12. The method according to claim 1, wherein, in said step of determining (step iii)), said Standard Set of Wavelengths comprises wavelengths from about 500 nm to about 1100nm.
- 20 13. The method according to claim 1, wherein in said step of obtaining (step (i)), said first absorbance measurements, said second absorbance measurements, or both said first and said second absorbance measurements, are determined one or more times at each wavelength of a wavelength calibration table, and either:
- 25 - an average of said first interpolated absorbance or said second interpolated absorbance value is mapped to said Standard Set of Wavelengths, or

- an average of said first absorbance measurements or an average of said second absorbance measurements is interpolated and mapped to a standard set of wavelengths.

- 5 14. The method according to claim 2, wherein, in said step of measuring (step (b)), said Standard Set of Wavelengths, used by both said first Apparatus and said Second Apparatus, are the same.
- 10 15. The method of claim 2, wherein, in said step of determining (step (iii)), and wherein in said step of measuring (step(b)), said standard set of wavelengths is derived from said first or said second wavelength calibration table.
- 15 16. The method according to claim 15, wherein said wavelength calibration table for said first apparatus or said second apparatus is obtained by:
- (i) projecting a first electromagnetic radiation of known wavelength, onto a first pixel of a first linear diode array of said first apparatus, or a second linear diode array of said second apparatus;
  - 20 (ii) using a second electromagnetic radiation of known wavelength, said second electromagnetic radiation having a different wavelength than said first electromagnetic radiation, projecting said second electromagnetic radiation onto a second pixel of said first or said second linear diode array;
  - (iii) identifying said first and second pixels within said first or said 25 second linear diode array;
  - (iv) calculating a pixel dispersion for said first or said second linear diode array; and
  - (v) assigning a wavelength to each pixel within said first or said second linear diode array to produce said wavelength calibration table using 30 said pixel dispersion and either said first electromagnetic radiation of known

wavelength, and said first pixel, or said second electromagnetic radiation of known wavelength and said second pixel.

17. The method according to claim 15, wherein said first wavelength  
5 calibration table for said first apparatus is obtained by:

- (a) projecting a known wavelength of electromagnetic radiation, onto a pixel in a linear diode array of said first apparatus;
- (b) identifying pixel number of said pixel;
- (c) assigning a wavelength to each pixel within said linear diode  
10 array to produce said wavelength calibration table using a predetermined pixel dispersion, said known wavelength of electromagnetic radiation, and said pixel number.

18. The method according to claim 17, wherein said steps of projecting  
15 (step (a)), identifying (step (b)), and assigning (step (c)) are repeated on said second apparatus, and wherein said electromagnetic radiation of known wavelength is projected onto a pixel of a second linear diode array of said second apparatus having said pixel number, whereby said first apparatus and said second apparatus produce said first and second wavelength calibration  
20 tables, respectively, and said wavelength calibration table is used as a standard set of wavelengths.

19. The method according to claim 17, wherein said steps of projecting  
(step (a)), identifying (step (b)), and assigning (step (c)) are repeated on said  
25 second apparatus, and wherein said electromagnetic radiation of known wavelength is projected onto a pixel of a second linear diode array of said second apparatus, having a different pixel number.

20 The method according to claim 19, wherein said standard set of  
30 wavelengths is obtained by:

(A) establishing a set of wavelengths common to said wavelength calibration table of both said first and said second apparatus; and

(B) selecting a range of wavelengths of said set of wavelengths, said range of wavelengths having wavelengths belonging to said standard set  
5 of wavelengths.

21. The method according to claim 18 wherein in said step of identifying (step (b)), an incorrect pixel is identified, said incorrect pixel is within less than or equal to about  $\pm N$  pixel, where, N is a number of pixels that encompass a  
10 range of wavelengths of no more than about 20 nm.

22. The method of claim 21 wherein said range of wavelengths is about  $\pm$  10 nm.

15 23. The method of claim 21 wherein said range of wavelengths is about  $\pm$  5 nm.

24. The method of claim 21 wherein said range of wavelengths is about  $\pm$  2 nm.  
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25. The method according to claim 2, wherein in said step of adjusting (step (c)), said adjusted interpolated absorbance is obtained using the following equation:

25 Adjusted Interpolated Absorbance = (interpolated absorbance - y-intercept) / slope;

wherein, interpolated absorbance is as determined in said step of measuring (step (b)); and "y-intercept" and "slope" are obtained from said first linear  
30 regression equation, where said First Linear Regression Equation is derived

from a plot of interpolated absorbance measurements, said first interpolated absorbance measurements on an X-axis, and said second interpolated absorbance measurements on a Y-axis, said First linear regression equation having a y-intercept and a slope.

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26. A method for Recalibrating an apparatus that is no longer in control, said apparatus comprising a Primary Calibration Algorithm transferred according to the method to claim 1, said method comprising:

(i) obtaining absorbance measurements of a set of calibrators on  
10 said apparatus, said set of calibrators having assigned absorbance values, said apparatus comprising a Primary Calibration Algorithm;

(ii) determining interpolated absorbance values for said absorbance measurements for at least one wavelength of a Standard Set of Wavelengths;

15 (iii) establishing a Second Linear Regression Equation in said apparatus, using said interpolated absorbance values and said assigned absorbance values; and

(iv) incorporating said Second Linear Regression Equation on said apparatus to produce a recalibrated apparatus.

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27. A method of determining the concentration of an analyte in a sample in a Recalibrated apparatus comprising:

(a) recalibrating said apparatus according to the method of claim  
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25 (b) measuring an absorbance measurement of said sample;

(c) deriving an interpolated absorbance for said absorbance measurement for at least one wavelength of said Standard Set of Wavelengths in said recalibrated apparatus;

(d) adjusting said interpolated absorbance measurement with said Second Linear Regression Equation to obtain an Adjusted Interpolated Absorbance; and

(e) calculating a concentration for said analyte by applying said  
5 Primary Calibration Algorithm for said analyte to said Adjusted Interpolated Absorbance.

28. The method according to claim 26 wherein in said step of obtaining (step (i)), said assigned absorbance values and said Primary Calibration  
10 Algorithm, and wherein in said step of incorporating (step(iv)), said second linear regression equation, are electronically stored.

29. The method according to claim 27, wherein in said step of obtaining (step (i)) said set of calibrators, and in said step of measuring (step (b)) said  
15 samples are placed within a like vessel having optical properties substantially similar to that used for Primary Calibration.

30. The method according to claim 27, wherein in said step of measuring (step (b)), said sample is any biological or non-biological fluid, and said  
20 analyte is any substance in said sample that can be measured.

31. The method according to claim 27, wherein in said step of measuring (step(b)), said sample is a solid, and said analyte is any substance in said sample that can be measured.

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32 The method according to claim 29, wherein said vessel is selected from the group consisting of a pipette tip, a labeled test tube, an unlabeled test tube, blood bag tubing, a transparent sample container, and a translucent sample container.

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33. The method according to claim 26 wherein in said step of obtaining (step (i)), two or more Calibrators are used.

34. The method according to claim 33, wherein said set of calibrators, used on a First Apparatus and said Apparatus, are from the same batch.

35. The method according to claim 33, wherein said set of calibrators comprise any material suitable for simulating absorbances and for producing at least one of said Second Linear Regression Equation.

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36. The method according to claim 35, wherein said set of calibrators used on a First Apparatus are the same as said set of calibrators used on said Apparatus.

15 37. The method according to claim 27, wherein in said step of determining (step ii), said Standard Set of Wavelengths comprise wavelengths from about 300nm to about 2500 nm.

38. The method according to claim 27, wherein, in said step of determining (step ii), said Standard Set of Wavelengths comprise wavelengths from about 500 nm to about 1100nm.

39. The method according to claim 27, wherein in said step of obtaining (step (i)), said absorbance measurements are determined one or more times at each wavelength of a wavelength calibration table, and either:

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- an average of said first interpolated absorbance value is mapped to said Standard Set of Wavelengths, or
- an average of said first absorbance measurements is interpolated and mapped to a standard set of wavelengths.

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40. The method according to claim 27, wherein in said step of adjusting (step (d)), said adjusted interpolated absorbance is obtained using the following equation:

5      Adjusted Interpolated Absorbance = (interpolated absorbance - y-intercept) / slope;

wherein, interpolated absorbance is as determined in said step of deriving (step (c)); and "y-intercept" and "slope" are obtained from said Second Linear  
10 Regression Equation, where said Second Linear Regression Equation is derived from a plot of electronically stored assigned absorbance measurements on an X-axis, and said interpolated absorbance measurements obtained on said recalibrated apparatus on a Y-axis, said Second linear regression equation having a y-intercept and a slope.

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41. A method for Calibrating an apparatus comprising:

- (i) obtaining absorbance measurements of a Set of Calibrators on said apparatus, said apparatus lacking a primary calibration algorithm, and said set of calibrators having assigned absorbance values,
- 20      (ii) determining interpolated absorbance values for said absorbance measurements for at least one wavelength of a Standard Set of Wavelengths;
- (iii) establishing a Second Linear Regression Equation in said apparatus, using said interpolated absorbance measurements and said  
25 assigned absorbance values; and
- (iv) incorporating said Second Linear Regression Equation, and at least one Primary Calibration Algorithm on said apparatus, to produce a calibrated apparatus.

42. A method of determining a concentration of an analyte in a sample in a calibrated apparatus comprising:
- (a) calibrating said apparatus according to the method of claim 41;
  - (b) measuring an absorbance value of said sample;
  - 5 (c) deriving an interpolated absorbance from said absorbance value for at least one wavelength of said Standard Set of Wavelengths in said calibrated apparatus;
  - (d) adjusting said interpolated absorbance measurement with said Second Linear Regression Equation to obtain an Adjusted Interpolated Absorbance; and
  - 10 (e) calculating a concentration for said analyte by applying said Primary Calibration Algorithm for said analyte to said Adjusted Interpolated Absorbance.
- 15 43. The method according to claim 41, wherein said step of obtaining (step (i)), said assigned absorbance values were obtained on an apparatus used to derive said at least one Primary Calibration Algorithm, wherein said apparatus was in control.
- 20 44. The method according to claim 41, wherein in said step of obtaining (step (i)), said assigned absorbance values, and wherein in said step of incorporating (step (iv)), said at least one second linear regression equation, and said at least one Primary Calibration Algorithm are electronically stored.
- 25 45. The method according to claim 42, wherein, in said step of obtaining (step (i)), and said step measuring (step (b)), said set of calibrators and said sample, are placed within a like vessel having optical properties substantially similar to that used for the Primary Calibration.

- 46 The method according to claim 42, wherein in said step of measuring (step (b)), said sample is any biological or non-biological fluid, and said analyte is any substance in said sample that can be measured.
- 5 47. The method according to claim 42, wherein in said step of measuring (step(b)), said sample is a solid, and said analyte is any substance in said sample that can be measured.
48. The method according to claim 45, wherein said vessel is selected  
10 from the group consisting of a pipette tip, a labeled test tube, an unlabeled test tube, blood bag tubing, a transparent sample container, and a translucent sample container.
49. The method according to claim 41, wherein in said step of obtaining  
15 (Step (i)), two or more Calibrators are used.
50. The method according to claim 49, wherein said set of calibrators, used on a First Apparatus and said Apparatus, are from the same batch.
- 20 51. The method according to claim 49, wherein said set of calibrators comprise any material suitable for simulating absorbances and for producing at least one of said Second Linear Regression Equation.
52. The method according to claim 49, wherein said set of calibrators used  
25 on a First Apparatus are the same as said set of calibrators used on said Apparatus.
53. The method according to claim 41, wherein in said step of determining (step ii), said Standard Set of Wavelengths comprise wavelengths from about  
30 300nm to about 2500 nm.

54. The method according to claim 41, wherein, in said step of determining (step ii), said Standard Set of Wavelengths comprise wavelengths from about 500 nm to about 1100nm.

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55. The method according to claim 41, wherein in said step of obtaining (step (i)), said absorbance measurements are determined one or more times at each wavelength of a wavelength calibration table, and either:

- an average of said first interpolated absorbance value is mapped to  
10 said Standard Set of Wavelengths, or
- an average of said first absorbance measurements is interpolated and mapped to a standard set of wavelengths..

56. The method according to claim 42, wherein, in said step of measuring  
15 (step (b)), said Standard Set of Wavelengths, used by both a first Apparatus and the Apparatus being calibrated, are the same.

57. The method according to claim 42, wherein in said step of adjusting (step (d)), said adjusted interpolated absorbance is obtained using the  
20 following equation:

Adjusted Interpolated Absorbance = (interpolated absorbance - y-intercept) / slope;

25 wherein, interpolated absorbance is as determining in said step of deriving (step (c)); and "y-intercept" and "slope" are obtained from said Second Linear Regression Equation, where said Second Linear Regression Equation is derived from a plot of electronically stored assigned absorbance measurements on an X-axis, and said interpolated absorbance

measurements obtained on said calibrated apparatus on a Y-axis, said Second linear regression equation having a y-intercept and a slope.

58. The method according to claim 2, wherein in said step of obtaining  
5 (step (i)), said set of calibrators is from a second batch, and in said step of determining (step (iii)), only said first interpolated absorbance is determined.

59. The method according to claim 58, wherein said first interpolated absorbance is assigned to said calibrators.

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60. A method according to claim 59 wherein said second batch of calibrators comprise any material suitable for simulating absorbances and for producing said set of first linear regression equations by plotting interpolated absorbances between a First Apparatus on one axis and a Second  
15 Apparatus on the other axis.

61. The method according to claim 2, wherein in said step of measuring (step (b)), said sample is one or more calibrators from a second batch, and said second apparatus is in control, and wherein in said step of adjusting  
20 (step (c)), said adjusted interpolated absorbance is obtained for said one or more calibrators.

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62. The method according to claim 61, wherein said adjusted interpolated absorbance is assigned to said set of calibrators from said second batch.

63. A method according to claim 62 wherein said second batch of calibrators comprise any material suitable for simulating absorbances and for producing said set of first linear regression equations by plotting measured absorbances between a First Apparatus on one axis and a Second  
30 Apparatus on the other axis.

64. The method according to claim 27, wherein in said step of obtaining (step (i)), said set of calibrators is from a first batch, and wherein in said step of measuring (step (b)), said sample is one or more calibrators from a second  
5 batch.

65. The method according to claim 64, wherein in said step of adjusting (step (d)), said adjusted interpolated absorbance is assigned to said second batch of calibrators.

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66. A method according to claim 65 wherein said second batch of calibrators comprise any material suitable for simulating absorbances and for producing said set of first linear regression equations by plotting measured absorbances between a First Apparatus on one axis and a Second  
15 Apparatus on the other axis.

67. A method according to claim 16 wherein in said step of calculating said pixel dispersion is determined by averaging pixel dispersion derived from more than one apparatus.

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68. A medium storing instructions adapted to be executed by a processor to determine analyte concentration within a sample as defined by the method of claim 2, said instructions comprising

- i) said at least one primary calibration algorithm;
- 25 ii) assigned absorbances of said set of calibrators obtained from said first apparatus; and
- iii) identity of said first apparatus used to obtain said at least one primary calibration algorithm and said assigned absorbances :

69 A medium storing instructions adapted to be executed by a processor to determine analyte concentration within a sample as defined by the method of claim 27, said instructions comprising

- i) assigned absorbances of said set of calibrators obtained from a first apparatus; and
- ii) identity of said first apparatus used to obtain said at least one primary calibration algorithm and said assigned absorbances.

70. A medium storing instructions adapted to be executed by a processor to determine analyte concentration within a sample, as defined by the method of claim 42, said instructions comprising

- i) said at least one calibration algorithm;
- ii) assigned absorbances of said set of calibrators obtained from a first apparatus; and
- iii) identity of said first apparatus used to obtain said at least one primary calibration algorithm and said assigned absorbances.

71 A kit comprising said set of calibrators, said medium of claim 68, and instructions for use.

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72. The kit of claim 71, wherein said set of calibrators are any type of calibrators suitable for producing one or more said first linear regression equations based on interpolated absorbances obtained using a first apparatus that is in control and interpolated absorbances obtained using a second apparatus.

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73. A kit comprising said set of calibrators, said medium of claim 69, and instructions for use.



74. The kit of claim 73, wherein said set of calibrators are any type of calibrators suitable for producing one or more said second linear regression equations based on interpolated absorbances obtained using a first apparatus that is in control and interpolated absorbances obtained using a  
5 second apparatus.

75. A kit comprising said set of calibrators, said medium of claim 70 and instructions for use.

10 76. The kit of claim 75, wherein said set of calibrators are any type of calibrators suitable for producing one or more said second linear regression equations based on interpolated absorbances obtained using a first apparatus that is in control and interpolated absorbances obtained using a second apparatus.

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77. An apparatus for determining analyte concentration of a sample comprising a spectrophotometer, a light source, a power supply, a sample holder, a circuit board, a primary calibration algorithm, and said first linear regression equation as defined in claim 2.

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78. An apparatus for determining analyte concentration of a sample comprising a spectrophotometer, a light source, a power supply, a sample holder, a circuit board, a primary calibration algorithm, and said second linear regression equation as defined in claim 27.

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79. An apparatus for determining analyte concentration of a sample comprising a spectrophotometer, a light source, a power supply, a sample holder, a circuit board, a primary calibration algorithm, and said second linear regression equation, as defined in claim 42.

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80. A system for determining presence of an analyte comprising

i) means for transmitting electromagnetic radiation of one or more known wavelengths through a sample;

5 ii) means for detecting electromagnetic radiation after transmission through said sample;

iii) means for incorporating a primary calibration algorithm,

iv) means for storing a wavelength calibration table and a standard set of wavelengths;

10 v) means for deriving a first linear regression equation, a second linear regression equation, or both a first and a second linear regression equation;

vi) means for detecting presence or concentration of an analyte within said sample.